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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,951	08/28/2003	Jia-He Li	70003.0002USD1	6259
30678	7590	02/09/2005	EXAMINER	
CONNOLLY BOVE LODGE & HUTZ LLP			COVINGTON, RAYMOND K	
SUITE 800			ART UNIT	
1990 M STREET NW			PAPER NUMBER	
WASHINGTON, DC 20036-3425			1625	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/649,951

Applicant(s)

LI ET AL.

Examiner

Raymond Covington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/26/03, 1/22/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 47-60 is/are pending in the application.
- 4a) Of the above claim(s) 58-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 47-60 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/26/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Applicants' election of Group II, claims 47-57, with traverse with the additional election of the species of claim 49 have been noted and considered. However, the restriction is deemed sound for reasons of record and hereby maintained. In addition to claim 49, claims 48 and 50-57 will be searched to the extent they read on the elected species where the corresponding Z groups of formula IV in claim 47 are pyridyl substituents and where (R<sup>3</sup>) and (R<sup>4</sup>) of substituent N(R<sup>3</sup>)(R<sup>4</sup>) together with the attached Nitrogen atom form a pyridyl ring substituent.

Upon determination of allowable subject matter the method claims, 58-60 that depend from or otherwise include all the limitations of the patentable product will be considered for rejoinder.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Claims that are not commensurate in scope with an allowed product claim will not be rejoined. In order to retain the right to rejoinder Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise

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include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-57 are rejected under 35 U.S.C. 112, first paragraph, as lacking enabling disclosure. The claim(s) contain subject matter to support the claimed compounds, prod rugs and salts. However, the specification, page 24-25 does not contain enabling disclosure for “metabolite”.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in Ex parte Forman 230 USPQ 546. The factors include:

- 1) quantity of experimentation necessary,
- 2) the amount of guidance presented,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the predictability of the art,
- 7) breath of the claims and
- 8) the level of skill in the art.

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A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, In re Glass, 181 USPQ 31; 492 F.2d 1228 (CCPA 1974).

The specification provides only a description that metabolites per se are known and that they have physical properties, which differ from the original product. The specification language describes and gives an example for how metabolite properties may differ but does not disclose metabolites for the claimed compounds, their properties and activities.

While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention. Presently, the instant method is not seen as supported by the written description and the instant disclosure would not enable a person skilled in the art to prepare products by the recited process. Examples and description are not of sufficient scope to provide enablement for the scope of the claims. More than routine experimentation would be required to place such a vast spectrum of compounds in possession of the public.

Claim 55 is rejected under 35 U.S.C. 112, first paragraph, as lacking enabling disclosure. Claim 50 recites the composition of claim 50 to be a solid implant. The specification at page 31 line 18 discloses that the composition may be molded into a solid implant. It is not clear from the specification whether the implant is a solid material inserted into the biodegradable polymer or an implant for insertion into the body.

Claims 53 and 54 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Both claims 53 and 54 refer to a method step, which is not present or supported in claim 50 which, is drawn to a composition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 47, along with claims 48-57 which ultimately depend from it, are rejected under 35 U.S.C. 112 second paragraph. The term  $N(R^3)(R^4)$  is not clear because it lacks a point of attachment. For purposes of

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examination it is assumed that the point of attachment to the moiety is via nitrogen atom.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shemano US 4,041,165 and Shemano US 3,937,833.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Shemano US 4,041,165 and Shemano US 3,937,833 teach related fluoranthene derivatives. See for example, column 2 lines 15-38 and formula II of Shemano '165 and '833.

***Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)***

Patentees differ in that the compounds contain piperidine instead of pyridyl attached to the bi substituted linking groups.

***Finding of prima facie obviousness—rational and motivation (MPEP §2142-2413)***

However, the references read on heteroaryl substituents per se.



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This corresponds to and is inclusive of the claimed pyridyl substituents taught by applicants. It would have been obvious to one of ordinary skill in the art to use one heteroaryl, e.g. pyridyl, in lieu of another, as the results would not have been unexpected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access

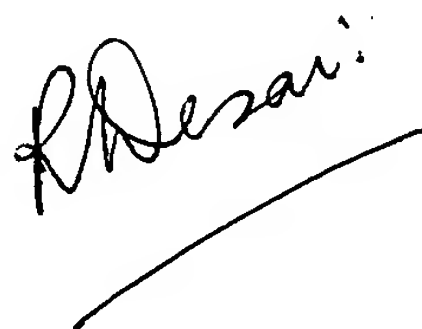


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to the Private PAIR system, contact the Electronic Business Center (EBC) at  
866-217-9197 (toll-free).

Raymond Covington  
Examiner  
Art Unit 1625

  
RKC

  
2/7/05